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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/363,748

07/30/99

WATKINS

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PEPPER HAMILTON LLP
GILBERTO M VILLACORTA
600 FOURTEENTH STREET N W
WASHINGTON DC 20005-2004

EXAMINER

CRANE, L

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

10/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/363,748

Applicant(s)
Watkins et al.

Examiner
L. E. Crane

Group Art Unit
1623

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/30/99, 10/18/99 & 12/2/99 (Preambts A&B, IDS)
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed in** accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-38 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-38 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 8 ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

- 5 The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. §1.67(a) identifying this application by its Serial Number and filing date is required. See MPEP 602.01 and 602.02. The oath or declaration is defective because:

- 10 The instant declaration is a Xerox copy of the originally signed document. Applicant is respectfully requested to either submit the originally executed declaration or a new and originally executed declaration in place of the instant copy.

- 15 No claims have been cancelled, two preliminary amendments have been entered, and an Information Disclosure Statement (IDS) has been received and made of record as of the date of the instant Office action.

Claims 1-38 remain in the case.

- 20 Claims 1-38 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Inspection of the instant disclosure reveals no specific test data to support either the generic or the more specific claim limitations directed to the treatment of an specific disease condition or conditions by the

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administration of uridine, cytidine, mixtures of uridine and cytidine, or any other uridine- or cytidine-containing binary or higher order mixtures of active ingredients. Therefore, the instant disclosed exemplifications relevant to the instant claims are deemed to be entirely prospective and
5 therefore lacking any enabling effect.

Claims 1-38 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 2, the term "a uridine source" is non-standard claim
10 language and is therefore unclear. Is applicant referring to -- A pharmaceutical composition comprising uridine and a pharmaceutically acceptable carrier.-- ? A similar problem arises in claims 14-15 wherein it is also unclear what precisely applicant is making reference to. A solution to these problems consistent with
15 standard US patent practice is respectfully requested.

In claim 5, lines 1-3, the term Markush group is incorrect; e.g. Markush groups are properly formulated with the term -- selected from the group consisting of [A], [B], ... and [R] -- but the terms "and/or" and the like are not properly part of this format. In addition, at line 2, the term
20 "like" suggests that said term is synonymous with --for example-- and --such as--, is therefore per se indefinite, and therefore should be deleted. The same problem reoccurs in claim 21.

In claims 6 and 20, the term "lack of attention, alertness, concentration, focus, or dyslexia" incorporates a dangling participle; e.g.
25 does one of ordinary skill care to treat "lack of dyslexia--?

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5 In claims 7 and 21, lines 2-3, the term "comprising mania, ... and bipolar disorders" is confusing. Is the claim directed to the individual or separate treatment of each of the listed disease conditions, or to an individual suffering from all of these conditions simultaneously as implied by the term "comprising?"

10 In claims 7 and 21, the term "dysthemia" appears to be a misspelling. Did applicant intend the term to be spelled -- dysthymia--? Examiner has found the second term in Taber's Cyclopedic Medical Dictionary (def. mild, chronic depression lasting two years or more and occurring in women twice as frequently as in men).

In claims 11 and 25, the term "neurological disorders are behavioral and neurological syndromes" is a misstatement. Appropriate clarification is respectfully requested.

15 In claims 13 and 27, the term "like" is used in a manner suggesting the intended meaning is synonymous with "preferably" and is therefore indefinite and should be deleted. If applicant wishes to obtain the lost subject matter, -- dependent claims -- are one possible and appropriate means to achieve this result.

20 In claim 16, lines 2-3, the term "and other compounds" is indefinite for failure to define which "other compounds" are properly included within the scope of the claimed subject matter.

25 In claim 18, the term "memory decline associated with brain aging" is indefinite for failure to define the period of a host brain age to which the instant claim is making reference; i.e. brain aging begins to occur at birth.

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In claim 30, lines 2-3, the term "stearate selected from choline chloride, choline bitartrate, ..." is technically incorrect and confusing. Correction and clarification is respectfully requested.

5 The Markush group in claim 31 is incorrectly formulated. See rejection above for guidance.

In claim 31, the term "e.g." is per se indefinite as lacking appropriate metes and bounds.

In claim 32, line 2, the term "patient=s" is apparently a misspelling. Did applicant intend the term to read -- patient's --?

10 Claim 36 is now dependent on claim 29 and therefore incorrectly refers to "a mixture of compounds." Because of the change in dependence, claim 36 now appears to have been rendered a duplicate of claim 29. Cancellation or other appropriate actions is respectfully requested.

15 The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

20 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

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Claims 1-38 are rejected under 35 U.S.C. §102(b) or (e) as being anticipated by any one of PTO-892 references B, L, R, S, T, U, V, W X, Y and Z.

5 Applicant is referred to each of the noted references wherein various uridine and uridine/cytidine mixtures and/or prodrugs mixtures are used to treat various neurological disease conditions including those of cerebral origin.

10 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not
15 commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

20 Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are (703) 308-4556 and 703-305-3592 .

25 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639 . The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

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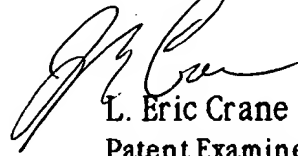
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached at (703)-308-1701.

5 Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235 .

LECrane:lec
10/10/00


L. Eric Crane
Patent Examiner
Group 1600